IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No:	09/898,936
Appellant:	Paul DiCarlo
Filed:	July 3, 2001
Title:	IMPLANT HAVING IMPROVED FIXATION TO A BODY LUMEN AND METHOD FOR IMPLANTING THE SAME
TC/A.U.:	3738
Examiner:	Kamrin R. Landrem
Confirmation No.:	1985
Notice of Appeal Filed:	September 10, 2004
Docket No.:	BSI-479US

APPEAL BRIEF

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S I R :

In response to the Official Action dated September 7, 2004, Appellant is submitting this Appeal Brief for the above-identified application.

I. REAL PARTY IN INTEREST

The Real Party in Interest in this matter is SciMed Life Systems, Inc.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellant, Appellant's legal representative, or Assignee which may be related to, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 16-24 and 28-34 are canceled. Claims 1-15, 25-27, and 35-52 are pending and stand rejected. Claims 1-15, 25-27, and 35-52, all the pending claims, are being

appealed. Of the pending appealed claims, claims 1, 25, 35-38, and 41-43 are independent.

IV. STATUS OF AMENDMENTS

The present application is under final rejection. Appellant submitted a response under 37 C.F.R. §1.116 on July 20, 2004, that included a request for reconsideration and supporting arguments. Appellant submitted no changes to the claims in that response. The Advisory Action of September 7, 2004, refused entry of that response. The arguments submitted by Appellant are nonetheless properly part of the record on appeal. Those arguments are repeated with additional support as set forth below.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claims 1, 25, 35-38, and 41-43 are appealed. The claimed invention is directed to an implant having improved fixation to a body lumen and methods for its implantation. Generally, the inventive device provides a prosthetic component having a graft and a hem formed on the graft, wherein the hem defines an interior space. The device further provides a cord disposed in this interior space and adapted for expanding upon absorbing fluid. As recited by claim 1, for example, the cord serves to aid in fixating the prosthetic component against the body lumen. Each of the independent device claims recites an alternative configuration by, for example, varying the number, location, permeability, and ductility of the hemmed portions.

Independent claims 1, 35-38, and 41 recite device embodiments of the disclosed invention. Independent method claims 25 and 42 generally recite introducing the inventive device into a body lumen and then contacting the cord with fluid, while independent method claim 43 recites introducing a device of the invention into a body lumen and then removing

an impediment to fluid flow to allow the fluid to contact the cord.

In accordance with 37 C.F.R. § 41.37(c)(1)(v), a concise explanation of the subject matter defined in each of the nine independent claims is set for the below. Citations to the application's support for claimed subject matter are made by reference to page (*p.*) and line (*l.*) of appellant's specification (*AS*) as originally filed (e.g., *AS p. 1, l. 22 - p. 2, l. 9*) as well as corresponding figures (*Figs.*).

Claim 1

Independent claim 1 broadly recites a prosthetic device for surgical implantation in a body lumen. *Generally, AS p. 1, l. 22 - p. 2, l. 9; p. 4, l. 6 - p. 7 l. 21; and p. 12, l. 1 - l. 34; Figs. 1, 2, 6, and 9.* The claimed device comprises a graft having two ends: a proximal end and a distal end. *AS p. 4, l. 21 - 24.* The proximal end of the device refers to the end closer to the surgical access point from outside the patient's body. *Id.* The claimed device further includes a hemmed region formed on an end and having a cord disposed within that hem. *AS p. 4, l. 19 - p. 7, l. 21; Figs. 1, 2, and 6.* That cord is adapted to aid in fixating the device against a body lumen by expanding upon fluid absorption. *AS p. 5, l. 10 - p. 5, l. 13; Figs. 1, 2, and 6.*

Claim 25

Independent claim 25 broadly recites a method for implanting a prosthetic device in a body lumen. *Generally, AS p. 7, l. 22 - p. 9, l. 20; Figs. 7, 8A, 8B, and 8C.* The claimed steps of the method include introducing the device as recited in claim 1 into a body lumen and contacting the cord with fluid to aid in fixating the device to the body lumen. *AS p. 9, l. 5-20; Figs. 7, 8A, 8B, and 8C.*

Claim 35

Independent claim 35 also claims a device embodiment. Claim 35 differs from claim 1 in that it further recites a stent disposed radially within the graft. *AS p. 4, l. 6 - 18; Figs. 1 and 2.* Claim 35 also differs from claim 1 because it more broadly claims a hem formed on the graft without specifying the location of the hem. *AS p. 5, l. 10.* That is, claim 1 recites the hem as being formed on either end of the graft while claim 35 encompasses devices whose hems are located anywhere along the graft. *Id.* Thus claim 35 differs in scope from claim 1 by additional recitation of a stent element and more broadly claiming the disposed hem.

Claim 36

Independent claim 36 claims a further device embodiment. Claim 36 recites a prosthetic component having a hem at both its proximal and distal ends and a cord in each hem that is adapted to aid in fixating the device against a body lumen by expanding upon fluid absorption. *AS p. 7, l. 11 - 21; Fig. 1.*

Claim 37

Independent claim 37 claims a device embodiment and recites a prosthetic component having a hem at its distal end in which is disposed a cord adapted to aid in fixating the prosthesis wherein the cord has thickness of thirty-thousandths of an inch prior to being contacted with fluid. *AS p. 7, l. 26 - 33.*

Claim 38

Independent claim 38 recites a device embodiment: a prosthetic component including a graft having a ductile hem with a cord adapted to aid in fixating the prosthetic component upon contact with fluid. *AS p. 5, l. 18 - 20.* This claim is distinguishable from the previous claims by the recited limitation that the hem is "ductile."

Claim 41

Independent claim 41 claims a device comprising a prosthetic component having a graft with a hem formed on the graft. The hem portion has a different permeability from the remainder of the graft to adjust rate of fluid contact with the cord disposed within the hem.

Claim 42

Independent claim 42 recites a method of implanting a device. In particular, the claim includes the loading of a prosthetic device into an introducer, inserting and positioning the introducer into a body lumen, withdrawing the introducer to deliver the prosthesis, and contacting the cord with fluid to aid in fixating the prosthesis to the body lumen. *AS p. 9, l. 5-20; Figs. 7, 8A, 8B, and 8C.*

Claim 43

Independent claim 43 recites a further method of implanting a device embodiment of the present invention. The method includes loading the broadly claimed device into an introducer, aligning the outside circumference of the hem with the inside diameter of a body lumen, and removing an existing fluid flow barrier in the body lumen to permit fluid to contact the cord disposed within the hem. *AS p. 9, l. 17 - 20*; Fig. 8C.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-9, 11, 15, 25-27, 36-38, and 42-52 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,522,881 to Lentz (Lentz) in view of U.S. Patent No. 5,964,744 to Balbierz et al. (Balbierz). Claims 10, 14, and 41 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lentz as modified by Balbierz

further in view of U.S. Patent No. 5,769,884 to Solovay (Solovay). Claims 12, 13, 35, 39, and 40 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lentz as modified by Balbierz further in view of U.S. Patent No. 5,824,036 to Lauterjung (Lauterjung).

VII. ARGUMENT

A. ARGUMENT SUMMARY

1. THE OFFICE ACTION'S PROPOSED COMBINATION OF THE DISCLOSURES BY LENTZ AND BALBIERZ DOES NOT RENDER OBVIOUS APPELLANT'S INVENTION AS CLAIMED IN INDEPENDENT CLAIMS 1, 25, 36, 37, 42, AND 43 BECAUSE THERE IS NO MOTIVATION TO COMBINE THESE REFERENCES.

Independent claims 1, 25, 36, 42, 37, and 43 are patentable over the proposed combination of Lentz and Balbierz because there is no motivation to combine these references. To advance a *prima facie* case for obviousness, the PTO must identify a suggestion or motivation to combine the reference teachings found in the nature of the problem to be solved, the teachings of the prior art, or the knowledge of persons of ordinary skill in the art. *See In re Rouffet*, 149 F.3d 1350, 47 U.S.P.Q2d 1453 (Fed. Cir. 1998); *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573, 37 U.S.P.Q.2d 1626, 1630 (Fed. Cir. 1996); *Micro Chemical, Inc. v. Great Plains Chemical Co.*, 41 U.S.P.Q.2d 1238 (Fed. Cir. 1996); MPEP § 2143.01.

Appellant contests the motivation to combine Lentz and Balbierz on two grounds. First, there is no motivation to combine cited references because the proposed combination would produce a device unsatisfactory for the intended purpose of either reference. Second, there is no motivation to combine the applied references because the proposed

combination of references would change the principles of operation of the references. Accordingly, Appellant advances the following two lines of reasoning in opposition of the final rejection:

a. The proposed combination of Lentz and Balbierz would produce a device unsatisfactory for the intended purpose of either references; and

b. The proposed combination of Lentz and Balbierz would require changing the principles of operation of these references.

Either of these reasons, independently, is sufficient to overcome the Office Action's obviousness rejection. Nevertheless, Appellant respectfully submits that both reasons to overcome the proposed combination are applicable to the case under review. Therefore, the final rejection of claims 1, 25, 36, 42, and 43 as unpatentable over Lentz in view of Balbierz should be reversed. Further, the Final Rejection of dependent claims 2-11, 14, 15, 26, 27, 38, 41, and 44-52 should also be reversed because they ultimately depend from these independent claims. *See In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed Cir. 1988); MPEP § 2143.03.

2. THE COMBINED DISCLOSURES OF LENTZ AND BALBIERZ CANNOT SUPPORT A *PRIMA FACIE* CASE OF OBVIOUSNESS AGAINST INDEPENDENT CLAIMS 1, 25, 36, 37, 42, AND 43 BECAUSE THEIR PROPOSED COMBINATION DOES NOT TEACH OR SUGGEST "A CORD... ADAPTED FOR EXPANDING UPON ABSORBING FLUID FOR AIDING IN FIXATING [A] PROSTHETIC COMPONENT AGAINST [A] BODY LUMEN."

Independent claims 1, 25, 36, 37, 42, and 43 are patentable over the proposed combination of Lentz and Balbierz because the proposed combination fails to teach or to suggest at least one of the recited claim limitations. *See In re Wilson*, 424 F.2d 1382, 165

U.S.P.Q 494 (CCPA 1970); *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974); MPEP § 2143.03.

It is settled law that the PTO bears an initial burden of establishing a *prima facie* case in advancing a rejection for obviousness under § 103(a). *In re Spada*, 911 F.2d 705, 15 U.S.P.Q.2d 1655 at n.3 (Fed. Cir. 1990). Establishing its *prima facie* case for obviousness requires the PTO to provide three elements: Suggestion or motivation to combine the reference teachings; a reasonable expectation for success; and the combined teachings of the references must teach or suggest all claim limitations. *See In re Vaeck,* 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

Appellant challenges the proposed combination of Lentz and Balbierz because the references fail to teach or suggest:

> ... a cord disposed within said interior space *adapted for expanding upon absorbing fluid for aiding in fixating said prosthetic component against said body lumen.* Appellant's claim 1 (emphasis added).

3. THE COMBINED DISCLOSURES OF LENTZ AND BALBIERZ CANNOT SUPPORT A *PRIMA FACIE* CASE OF OBVIOUSNESS AGAINST INDEPENDENT CLAIM 36 BECAUSE THE PROPOSED COMBINATION DOES NOT TEACH OR SUGGEST "A STENT RADIALLY DISPOSED INSIDE [THE] GRAFT" TOGETHER WITH "A CORD... ADAPTED FOR EXPANDING UPON ABSORBING FLUID FOR AIDING IN FIXATING [A] PROSTHETIC COMPONENT AGAINST [A] BODY LUMEN."

Appellant's claim 36 is directed to a prosthesis having a graft with a stent radially disposed therein and further comprising the absorbent cord feature described above. Appellant's challenges to the proposed combination of the disclosures Lentz and Balbierz are

fortified with respect to claim 36 because it recites an additional feature: a stent disposed radially inside the graft. In contrast, Lentz contemplates a stent component only within its cuffs. Lentz, col. 5, l. 10-16; Figs. 4 and 7. Because the proposed combination of Lentz and Balbierz fails to meet this limitation, this distinction provides a further basis for distinguishing claim 36 from the prior art.

4. APPELLANT'S INVENTION AS CLAIMED IN INDEPENDENT CLAIMS 10, 14, AND 41 IS PATENTABLE OVER LENTZ AND BALBIERZ FURTHER IN VIEW OF SOLOVAY BECAUSE THERE IS NO MOTIVATION FOR THE PROPOSED COMBINATION AND THE PROPOSED COMBINATION DOES NOT TEACH OR SUGGEST "A CORD... ADAPTED FOR EXPANDING UPON ABSORBING FLUID FOR AIDING IN FIXATING [A] PROSTHETIC COMPONENT AGAINST [A] BODY LUMEN."

With respect to this rejection, Appellant restates the same arguments presented to oppose the rejections based on Lentz and Balbierz alone. The reasoning is equally persuasive with respect to this rejection based upon the addition of the Solovay reference to the proposed combination of Lentz with Balbierz. Namely, that there is no motivation to combine Lentz and Balbierz and assuming, *arguendo*, that they are combined, they fail to meet every limitation of the rejected claims.

5. APPELLANT'S INVENTION AS CLAIMED IN INDEPENDENT CLAIMS 12, 13, 35, 39, AND 40 IS PATENTABLE OVER LENTZ AND BALBIERZ FURTHER IN VIEW OF LAUTERJUNG BECAUSE THERE IS NO MOTIVATION FOR THE PROPOSED COMBINATION AND THE PROPOSED COMBINATION DOES NOT TEACH OR SUGGEST "A CORD... ADAPTED FOR EXPANDING UPON ABSORBING FLUID FOR AIDING IN FIXATING [A] PROSTHETIC COMPONENT AGAINST [A] BODY LUMEN."

With respect to this rejection, Appellant restates the same arguments presented to oppose the rejections based on Lentz and Balbierz alone. The reasoning is equally persuasive with respect to this rejection based upon the addition of the Lauterjung reference to the proposed combination of Lentz with Balbierz. Namely, that there is no motivation to combine Lentz and Balbierz and assuming, *arguendo*, that they are combined, they fail to meet every limitation of the rejected claims.

B. ISSUE

All the appealed claims stand rejected under 35 U.S.C. § 103(a) as obvious by a proposed combination of Lentz and Balbierz either alone or further in view of tertiary references Solovay or Lauterjung. Two rejections are premised solely on a proposed combination of Lentz and Balbierz. The third rejection relies further on Solovay. The fourth rejection combines Lentz and Balbierz along with Lauterjung. Therefore, the rejection of all claims is based ultimately upon the proposed combination of Lentz and Balbierz.

These are the only rejections; there are no other rejections and no other applied references. The issue on appeal is whether the cited references may be properly combined and, if combined, whether they render Appellant's claimed invention obvious.

C. LEGAL STANDARD

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made. 35 U.S.C. § 103.

To advance a rejection for obviousness under § 103(a), the PTO must first present a *prima facie* case for obviousness. *In re Spada*, 911 F.2d 705, 15 U.S.P.Q.2d 1655 at n.3

(Fed. Cir. 1990). A *prima facie* case of obviousness requires three elements: suggestion or motivation to combine the reference teachings; a reasonable expectation for success; and the combined teachings of the references must teach or suggest all claim limitations. *See In re Vaeck,* 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

Appellant challenges the Office Action's *prima facie* case of obviousness on two grounds. The first ground is that there is no motivation to combine the reference teachings as proposed by the Office Action. Combining the references as suggested by the Office Action would render the prior art unsatisfactory for its intended purpose. *See In re Gordon,* 733 F.2d 900, 21 U.S.P.Q. 1125 (Fed. Cir. 1984); *In re Fritch*, 972 F.2d 1260, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992). Also, combining the references as suggested by the Office Action would change the principles of operation of the prior art inventions being modified. *See In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (CCPA 1959).

The second ground is that even if the references were combined as suggested by the Office Action, the proposed combination fails to teach or suggest all claim limitations. Failure of the combined references to teach or suggest all claim limitations negates obviousness. *See In re Wilson*, 424 F.2d 1382, 165 U.S.P.Q 494 (CCPA 1970); *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974); MPEP § 2143.03.

D. THERE IS NO MOTIVATION TO COMBINE THE TEACHINGS OF LENTZ WITH THE TEACHINGS OF BALBIERZ

1. The Proposed Combination of Lentz and Balbierz Would Produce an Inoperable Device Incapable of Performing the Intended Purposes of Either Reference.

The Federal Circuit has held that where references taken in combination would produce a seemingly inoperative device the references teach away from the combination

and thus cannot serve as predicates for a *prima facie* case of obviousness. *See In re Fritch*, 972 F.2d 1260, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992); *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984); *In re Sponnoble*, 405 F.2d 578, 160 U.S.P.Q. 237 (CCPA 1969). This principle has been explicitly adopted, with citations to *In re Gordon*, by the MPEP in § 2143.01.

In *Fritch*, the Board of Appeals upheld the rejection of applicant's claims to a landscape edging apparatus. *Fritch* at 1261. The disclosed invention comprised an "L"-shaped device. *Id.* The planar base was elongate, thin, and flexible. *Id.* at 1261-1262. The base was fused to an upright retaining portion for defining an enclosed space. *Id.* at 1262. The Fritch device was intended for use as a retainer for landscape fill in order to separate unmowable landscape fill from mowable lawn. *Id.*

The Examiner in *Fritch* rejected the applicant's claims as obvious under 35 U.S.C. § 103. *Id.* at 1261. In so doing, he relied upon a patent issued to Wilson on a "Grass Edging and Watering Device" in combination with a patent issued to Hendrix on a "Loose Material Retainer Strip." *Id.* at 1263.

The Court of Appeals reversed the Board's decision, citing a lack of motivation to combine the references. *Id.* at 1266. As a basis for reaching its conclusion, the Court noted: "Wilson lacks any suggestion or incentive to use its water conduit as a landscape retainer since this would arguably result in clogged sprinkler heads." *Id.* at 1265, citing *In re Gordon* in accompanying footnote.

In the case presently under review, the Examiner proposes a combination of Lentz with Balbierz. Lentz is directed to an implantable prosthesis having integral cuffs. Lentz Fig. 4. Lentz discloses, and contemplates, inserting only a stent into each of the cuffs and

expanding those stents to anchor the conduit in the body vessel. *Lentz col. 3, l. 31.* The cuffs define slots between the cuff and body where the stent is inserted. As described in Lentz, the cuffs are used to house a stent, which is used to affix the prosthesis in place by radial expansion against the inner wall of the body lumen, in a known manner. *Lentz, col. 3, l. 31-60, and col. 5, l. 18-21.* Thus, the only location contemplated by Lentz for a stent to be disposed is in cuffs, and the only component which is envisioned by Lentz to be disposed therein is a stent. As conceded in the Final Office Action, Lentz fails to disclose a cord disposed within the cuffs that is capable of absorbing fluid and expanding to aid in retention of the prosthesis within the body lumen. *FOA, p. 2.*

Balbierz is relied upon in the Final Office Action for its teaching of a device comprising a coated polymer material that expands upon hydration. *FOA, p. 2 citing Balbierz, col. 10, l. 46-48 and col. 7, l. 46-57.* The Final Office Action cites Figure 12 of Balbierz in support of the rejection. *FOA, p. 2.* As shown in Figure 12, and as described throughout Balbierz, its device is directed to a ureteral stent for assisting drainage, for example, from the kidney through the ureter. *Balbierz, col. 1, l. 26-28.* The parent patent of Balbierz, U.S. Patent No. 5,599,291 (the '291 patent) describes, at columns 4-5, the operation in more detail of a ureteral stent as illustrated in Figure 1 of both Balbierz and the '291 patent. The cited Balbierz device spans a narrowed passage of the target body lumen and is fixed in place by pigtail sections 803 and 804 on either end as shown in Fig. 1A. *Balbierz, col. 16, l. 43 - col. 17, l. 8; Figs. 12A, 12B, and 12C.*

Important to the prosthesis of Lentz is that its stent is sealed from the fluid flowing through the body vessel. *See* Lentz abstract, last sentence. More specifically, as described in Lentz at column 5, lines 28-35, the stent 28 is shown clearly supported in slot 24, meaning that the stent is never in direct contact with either blood flowing through the

lumen 32 or the tissue of the walls of vessel 34. *Lentz, Fig. 4.*

Therefore, merely placing the material of Balbierz et al. into the hem of Lentz would not achieve the result envisioned by the Examiner. In particular, because no body fluid would reach the material of Balbierz, it would not expand and then operate in the manner envisioned by the Examiner. On the contrary, body fluid would be prevented from contacting that material by inserting it into the hem of Lentz. Moreover, even if body fluid could have reached the material, configuring the device of Lentz into a position having an axis coincident with the axis of the body lumen would preclude body fluid from flowing along its "length" to cross a narrowed body lumen. Further still, by constraining the device of Balbierz et al. into the hem of Lentz in a hoop having an axis generally parallel to the body lumen, the principle on which Balbierz et al. relies on to keep it in place, namely abutting its pigtail design against a narrowing of the body lumen, would be ameliorated.

In short, because the Balbierz material residing within the Lentz hem would be unable to expand, the proposed combined device would not be operable as the supported graft envisioned by Lentz. Likewise, the proposed combined device has none of the pig-tail geometries emphasized in Balbierz as important in keeping the device in place and would thus be incapable of fixing itself within the ureteral passage as Balbierz intended. Therefore, one skilled in this art would not be motivated to combine these two disparate devices.

On a related issue, the Advisory Action of September 7, 2004 erroneously rejected this line of argument by Appellant when presented during prosecution. *Advisory Action, p. 2.* Without explanation, the Examiner quoted the following MPEP § 716(c) statement:

> The arguments of counsel cannot take the place of evidence in the record. Examples of attorney statements which are not evidence and which must be

> supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of long-felt need, inoperability of the prior art, invention before the date of reference, and allegations that the author(s) of the prior art derived the disclosed subject matter. *Id.*

The Examiner appears to have invoked this MPEP language as his basis for ignoring Appellant's argument with respect to the operability of the proposed combination of the prior art. If this is the case, the Examiner misapplies MPEP § 716(c). Section 716(c) interprets the rule promulgated at 37 C.F.R. §1.132 which calls for an oath or declaration when "evidence [is] submitted to traverse the rejection or objection on a basis not otherwise provided for... ." Here, Appellant traversed the operability of the *proposed combination* - not the individual reference inventions as is proscribed in § 716(c). In fact, both of Apellant's line of arguments challenging motivation to combine because of inoperability of the proposed combination and/or its change in principle of operation are "provided for" within the meaning of § 716(c) by the MPEP at § 2145(X)(D) and § 2143.01. Appellant is contending that no *prima facie* case of obviousness has been made out, so a discussion of secondary considerations, which are more typically supplied by way of a declaration or other evidence, is not needed.

2. The Proposed Combination of Lentz and Balbierz Would Change the Principle of Operation of the References.

The Court of Customs and Patent Appeals has held that where a proposed combination would change the principle of operation of the prior art invention being modified, then the teachings of the references are insufficient to support a case for *prima facie* obviousnesss. *See In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (CCPA 1992). This principle has been explicitly adopted, with citations to *In re Ratti*, by the MPEP in § 2143.01.

In *Ratti*, the Board of Appeals upheld the rejection of claims to the applicant's oil seal. *Ratti, 270 F.2d 810, 123 U.S.P.Q. 349.* The disclosure taught an annular ring seal for sealing around a shaft that was resilient and incorporated an "outwardly biased resilient spring fingers" to engage the surrounding housing. *Id. at 811, 123 U.S.P.Q. 350.* The claims were rejected as obvious based on a combination of the disclosures of patents to Chinnery et al. and Jepson. *Id. at 810, 123 U.S.P.Q. 349.* Chinnery taught a stiffened annular ring for sealing about a shaft. *Id. at 811, 123 U.S.P.Q. 350.* Jepson taught a ring gasket for sealing between the upper and lower levels of a coffee maker that incorporated a sleeve member with radially biased spring fingers to assist in engagement of the mouth of the lower vessel. *Id. at 812, 123 U.S.P.Q. 351.*

The Court of Appeals reversed the rejection, holding that "the suggested combination of references would require a substantial reconstruction and redesign of the elements shown in Chinnery et al. as well as a change in the basic principles under which the Chinnery et al. construction was designed to operate." *Id.* at 813, 123 U.S.P.Q. 353.

In the case presently under review, the Final Office Action bases its rejection on a proposed combination of a cuffed prosthesis taught by Lentz with a uretal stent taught by Balbierz. *FOA, p. 2-3.* As noted in further detail above, Lentz teaches a prosthesis comprising a cuff with a slot for inserting a stent designed to prevent contact between the stent and fluids flowing through the body. *Lentz abstract, final sentence; col. 5, l. 28-35.*

In contrast, Balbierz teaches a fluid-absorbing stent which *requires* hydration in order to assume its final configuration. Balbierz col. 3, l. 52 - col. 4, l. 7. Moreover, the Balbierz stent defines a lumen 32 extending its entire length with openings at both ends and may also include drainage holes 34. Balbierz col. 5, l. 13-17. The lumen is configured to

permit flow along this length. *Id.* In order to achieve its purpose, it is critical that the device of Balbierz be configured such that it allows flow along its length.

The principles of operation of the two devices are at odds. Because Lentz teaches isolation of its stent component from fluids while Balbierz requires exposure to fluids, one skilled in the art would not be motivated to combine these two devices because their successful combination would require substantial redesign.

E. THE PROPOSED COMBINATION OF LENTZ AND BALBIERZ DOES NOT TEACH OR SUGGEST ALL CLAIM LIMITATIONS

The Final Office Action of May 21, 2004 (FOA) rejected independent claims 1-8, 11, 15, 25-27, 36-38, 42-52 under 35 U.S.C. § 103(a) based upon Lentz in view of Balbierz. *FOA, page 2.* The Appellant traverses this rejection's basis in law and fact because the proposed combination does not teach or suggest:

> ... a cord disposed within said interior space *adapted for expanding upon absorbing fluid for aiding in fixating said prosthetic component against said body lumen.* Appellant's appealed claim 1 (emphasis added).

This claim limitation appears in each of Appellant's five appealed independent device claims 35-38 and 41 as well as independent method claim 43. A similar limitation appears in Appellant's independent method claims 25 and 42 – "a cord disposed within said interior space for expanding upon absorbing fluid" – and is followed by a step of contacting the cord with fluid to aid in fixation.

As will be discussed further below, Appellant's "adapted for" claim limitation was ignored during prosecution for the purpose of determining patentability. FOA, p. 3. This disregard was premised upon an erroneous notion that the "adapted for" limitation "did not

constitute a limitation in the patentable sense." *Id.*, citing *In re Hutchinson, 154 F.2d 135, 69 U.S.P.Q. 138 (CCPA 1946).*

Lentz is directed to an implantable prosthesis 10 having integral cuffs 20 and 22. *Lentz, Fig. 4.* Lentz discloses, and contemplates, inserting only a stent 28 into each of the cuffs and expanding those stents to anchor the conduit in the body vessel. *Lentz, col. 3 l. 31.* The cuffs define slots 20 and 22 between the cuff and body where the stent is inserted. As described in Lentz, the cuffs are used to house a stent, which is used to affix the prosthesis in place by radial expansion against the inner wall of the body lumen, in a known manner. *Lentz, col. 3, l. 31-60, and col. 5, l. 18-21.* Thus, the only location contemplated by Lentz for a stent to be disposed in Lentz is in cuffs 20 and 22, and the only component which is envisioned by Lentz to be disposed therein is a stent. As recognized in the Final Office Action, Lentz fails to disclose a cord disposed within the cuffs that is capable of absorbing fluid and expanding to aid in retention of the prosthesis within the body lumen. *FOA, p. 2.*

Balbierz is relied upon in the Final Office Action for its teaching of a device comprising a coated polymer material that expands upon hydration. *FOA, p. 2 citing Balbierz, col. 10, l. 46-48 and col. 7, l. 46-57.* The Final Office Action cites Figure 12 in support of the rejection. *FOA, p. 2.* As shown in Figure 12, and as described throughout Balbierz, Balbierz is directed to a ureteral stent for assisting drainage, for example, from the kidney through the ureter. *See, e.g., Balbierz, col. 1, l. 26-28.* The parent patent of Balbierz, U.S. Patent No. 5,599,291 (the '291 patent) describes, at columns 4-5, the operation in more detail of a ureteral stent as illustrated in Figure 1 of both Balbierz and the '291 patent. The cited Balbierz device spans a narrowed passage of the target body lumen and is fixed in place by pigtail sections 803 and 804 on either end as shown in Fig. 1A. *See*

Balbierz, col. 16, l. 43 - col. 17, l. 8; Figs. 12A-C.

Also, the Balbierz device must form a predetermined final cross-ureteral stent outer diameter to provide enhanced fluid passage from kidney 28 to bladder 22. *The '291 patent, col. 5, l. 4-9.* The Balbierz device defines a lumen 32 extending its entire length with openings at both ends and may also include drainage holes 34. *The '291 patent, col. 5, lines 13-17.* In sum, to achieve its purposes, it is critical that the device of Balbierz be configured such that it allows flow along its length.

It was conceded by the Examiner during prosecution that Lentz fails to disclose a cord disposed within its cuffs that is capable of absorbing fluid and expanding to aid in retention of the prosthesis within the body lumen. *FOA, p. 4.* Nor does Balbierz teach or suggest a cord, disposed within an interior space of a prosthesis component, adapted for expanding upon absorbing fluid for aiding in fixating the prosthesis against a body lumen.

Appellant further contests the legal basis cited by the Final Office Action for ignoring appellant's "adapted for" limitation. Specifically, Appellant seeks recognition from the Board that *Hutchinson* does stand for the principle invoked by the Examiner. In the alternative, Appellant seeks the Board's recognition that this reading of *Hutchinson* has since been bypassed by more recent case law.

Turning first to a review of *Hutchinson* itself, the Court of Customs and Patent Appeals in that case affirmed the decision of the Board of Appeals affirming the Examiner's rejection of certain product claims. *Hutchinson, 69 U.S.P.Q. 141.* Claim 42 was deemed representative and recited in its preamble:

> As an article of manufacture, adapted for use in the fabrication in the use of a metal template or the like suitable for metal-working operations, a laminated unit comprising a backing element .... *Id. at 140.*

The claim went on to recite other limitations within the body of the claim such as an adhesive and a surface paper bonded to the backing element by the adhesive. *Id.* In attempting to overturn the Board's holding, the applicant had emphasized various parts of the claim, including the preamble quoted above which contained the "adapted for" language. *Id.* The Court dealt with this language in one paragraph of *dicta*, saying merely:

> The first phraseology italicized by appellant is the introductory clause to the effect that the laminated article is "*adapted*" for use in making a template or the like. This does not constitute a limitation in any patentable sense. *Id. at 141.*

As Appellant explained during prosecution of the application under review, there are a number of alternative and more compelling reasons for the *Hutchinson* court's assertion. First, the disputed limitation appeared in the claim's preamble ("introductory clause" in the Court's language) and it is a basic principle of claim construction that a preamble limitations are not necessarily read into a claim. *See Allen Eng'g Corp. v. Bartell Indus., Inc., 299 F.3d 1336, 63 U.S.P.Q.2d 1769 (Fed. Cir. 2002)* ("Generally, the preamble does not limit the claims."); *Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 U.S.P.Q.2d 1161, 1164 (Fed. Cir. 1999)* ("... the preamble is of no significance to claim construction [where] it cannot be said to constitute or explain a claim limitation." (citations omitted)). Thus, the mere fact that the "adapted" language appeared in the claim's preamble is more than adequate justification for the Hutchinson court's *dicta*.

A second and equally sufficient reason for the holding in *Hutchinson* is that the court perceived the disputed limitation as no more than a "use" limitation and correctly discounted it because "[i]t is well established that the discovery of a new property or use of an old product does not render the old product patentable." *Harris Corp. v. IXYS Corp., 114 F.3d 1149, 43 U.S.P.Q.2d 1018 (Fed. Cir. 1997).*

Finally, a third and independent reason for holding of *Hutchinson* is that the limitation included the phrase "or the like" which has been recognized as rendering a claim indefinite. MPEP 2173.05(c), heading F, *citing Ex Parte Caldwell, 1906 C.D. 58 (Comm'r Pat. 1906)* (term "or like material" in context of a limitation "coke, brick, or like material" held to render claim indefinite because it was not clear how materials other than coke or brick had to resemble the two specified materials to satisfy claim limitations).

In short, the court's reasoning in *Hutchinson* is ambiguous and has support in at least three other well-recognized canons of claim construction. As such, Appellant respectfully submits that *Hutchinson* should not be recognized by this Board for the principle the Examiner proposes to invoke. Because the Examiner's rejection of *all* pending claims depends, ultimately, upon ignoring the "adapted for" structural limitations of the independent claims based upon an erroneous reading of *Hutchinson*, the rejection of all claims should be withdrawn.

In the alternative, Appellant respectfully urges that even if *Hutchinson once* stood for the theory that "adapted" claim language does not impart a patentably distinct feature to a claim, more recent appellate court decisions have dispelled that notion. In particular, Appellant directs the Board's attention to *In re Land and Rogers, 368 F.2d 866, 151 U.S.P.Q. 621 (C.C.P.A. 1966)* and *In re Venezia, 530 F.2d 956, 189 U.S.P.Q. 149 (C.C.P.A., 1976).*

Looking first to *Land*, the Board rejected claims directed to devices and methods incorporating mechanisms for "deferred diffusion" for facilitating instant photography with multilayer color films. *Land*, 368 F.2d 868, 151 U.S.P.Q. 624. Citing to references that disclosed multilayer color films, the Board rejected a claim that read:

> said color-providing substances associated with at least the inner photosensitive emulsion layers are *adapted to be rendered diffusible* in said liquid composition *only after at least substantial development of* the next outermost photosensitive layer has occurred. *Id.* at 881, 151 U.S.P.Q. 635 (emphasis added by court.)

The Court of Customs and Patent Appeals reversed. *Id.* at 884, 151 U.S.P.Q. 637. In its analysis, the *Land* court characterized the "adapted to" language as a functional limitation and applied that limitation to distinguish the claim from the prior art saying:

> It is true that the italicized portions are "functional" but we do not regard that as good ground to give them "no weight" in view of the third paragraph of *35 USC 112.* We give them weight and with this limitation we think claims 70 and 71 are limited to deferred diffusion built into the structure recited, thereby being limited to the actual invention disclosed and hence allowable... . *Id.* at 882, 151 U.S.P.Q. 635-636.

In the case now under review, Appellant maintains that the limitation:

> ... a cord disposed within said interior space *adapted for expanding upon absorbing fluid for aiding in fixating said prosthetic component against said body lumen*

should be accorded similar patentable weight because it imports into the claim a structural requirement that the recited cord be capable of expansion by absorption of fluid *and* to expand to such a degree as to assist in the prosthesis' fixation against a body lumen.

Another case closer on point than *Hutchinson*, and decided thirty years after *Hutchinson,* is *In re Venezia*. *Venezia* has been adopted with quotations by the MPEP to support the proposition that "adapted to" language serves to precisely define present structural attributes of interrelated component parts of the claimed invention. *MPEP § 2173.05(g).* In *Venezia*, the claim at issue was directed to a splice connector kit comprising a pair of sleeves of elastomeric material, electrical contact means adapted to be affixed to a terminus of an exposed conductor, and a pair of retaining members "adapted to" be positioned between the sleeves. *Venezia, 530 F.2d 956, 189 U.S.P.Q. 149.* The Board of Appeals had agreed with the Examiner that the claim did not comply with 35 U.S.C. §§ 101 and 112, second paragraph. *Id. at 958, 189 U.S.P.Q. 151.*

The Court of Customs and Patent Appeals in *Venezia*, however, held that "the claims do define the metes and bounds of the claimed invention with a reasonable degree of precision and particularity." *Id.* In particular, after quoting the elements reciting the "adapted to" language, the Court stated, "rather than being a mere direction of activities to take place in the future, *this language imparts a structural limitation to the sleeve*" (emphasis added). *Id. at 958, 189 U.S.P.Q. 152.*

In the case now under review, Appellant's limitation:

> ... a cord disposed within said interior space *adapted for expanding upon absorbing fluid for aiding in fixating said prosthetic component against said body lumen*

also complies with 35 U.S.C. §§ 101 and 112, second paragraph because it imparts upon the invention a present requirement that the structure of the cord be such that it be capable of expansion by absorption of fluid *and* to expand to such a degree as to assist in the prosthesis' fixation against a body lumen. As a valid limitation which imparts a structural limitation to the claimed device or method within the meaning of §§ 101 and 112, second paragraph, the "adapted for" element is entitled to patentable weight.

From the *Land* and *Venezia* cases it has since been established that "adapted" language can properly serve as a claim limitation as either a functional or structural limitation. *See also Pac-Tec, Inc. v. Amerace Corp., 903 F.2d 796, 901, 14 U.S.P.Q.2d 1871, 1876 (Fed. Cir. 1990), cert. denied, 502 U.S. 808 (1991)* (in determining whether a patent claim is invalid because it is anticipated by prior art, it is improper to disregard the preamble and all limitations that include "adapted to", "whereby", and "thereby"); *3-8 Chisum on Patents § 8.04.* Appellant therefore contends that the *Hutchinson* court's language relied upon by the Final Office Action has been superseded by more recent appellate decisions. Because the Examiner's rejection of *all* pending claims depends,

ultimately, upon ignoring the "adapted" structural limitations of the independent claims based upon an erroneous legal theory extracted from *Hutchinson*, the appellant respectfully submits that the rejection of all claims should be withdrawn.

F. CONCLUSION

Appellant has advanced two reasons that the pending claims are allowable over the cited prior art. First, none of the references, taken singly or in combination, teaches the "adapted for" limitation recited in each of the pending independent claims. Second, there is no motivation to combine the references as proposed by the Examiner.

Therefore, because the Examiner's rejection of independent claims 1, 25, 35-38, and 41-43, and the claims dependent thereon, rests upon an improper combination of Lentz in view of Balbierz, the rejections should be reversed. Such action is earnestly solicited.

Respectfully submitted,

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Attachment: Pending Claims
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Melissa Clemons

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VIII. CLAIMS APPENDIX

1. (Previously Presented) A device for implantation in a body lumen comprising:

a prosthetic component having a proximal end and a distal end and comprising a graft extending between said proximal end and said distal end and having a hem formed on said proximal end or said distal end, wherein said hem defines an interior space; and

a cord disposed within said interior space adapted for expanding upon absorbing fluid for aiding in fixating said prosthetic component against said body lumen.

2. (Original) The device of claim 1, wherein said prosthetic component further comprises a stent disposed radially inside of said graft.

3. (Previously Presented) The device of claim 1, wherein said hem is disposed at said distal end of said prosthetic component.

4. (Previously Presented) The device of claim 3, wherein said graft further comprises a second hem disposed at said proximal end of said prosthetic component and defining a second interior space and said device further comprises a second cord disposed within said second interior space.

5. (Original) The device of claim 3, wherein said cord is in a compressed state prior to being contacted with fluid.

6. (Original) The device of claim 5, wherein the thickness of said cord in the compressed state is less than thirty thousandths of an inch.

7. (Original) The device of claim 1, wherein said cord has a flat ribbon shape.

8. (Original) The device of claim 1, wherein said cord has a shape selected from the group consisting of annular, circular, semi-circular, D-shaped, rectangular, octagonal, trapezoidal, triangular, and square.

9. (Original) The device of claim 1 further comprising an outer coating formed over said cord, wherein said coating dissolves upon exposure to fluid for varying the rate at which said cord expands after deployment of said device.

10. (Original) The device of claim 1, wherein said hem has holes to adjust the porosity of said hem for allowing fluid to contact said cord.

11. (Original) The device of claim 1, wherein said hem is sufficiently ductile to conform to irregular shapes.

12. (Original) The device of claim 2, wherein said hem is positioned to allow said stent to protrude distally relative to said hem.

13. (Original) The device of claim 12, wherein at least one hoop of said stent is distal relative to said hem.

14. (Original) The device of claim 1, wherein said graft has a first permeability at areas remote from said hem and a second permeability, greater than said first permeability, at said hem.

15. (Original) The device of claim 1 further comprising an attachment tab having a first part attached to the graft and a second part extending radially outward of said first part for attachment to an adjacent area of the body surrounding the prosthetic component.

16. - 24. (Canceled)

25. (Previously Presented) A method for implanting a device in a body lumen comprising the steps of:

introducing a device into a body lumen, wherein said device comprises: a prosthetic component having a proximal end and a distal end and comprising a graft extending between said proximal end and said distal end and having a hem formed on said proximal end or said distal end, wherein said hem defines an interior space; and a cord disposed within said interior space for expanding upon absorbing fluid; and

contacting said cord with fluid to aid in fixating said prosthetic component against said body lumen.

26. (Original) The method of claim 25, wherein introducing said device comprises the following steps:

compressing the device into an introducer;

inserting the introducer into the body lumen;

positioning the introducer such that the compressed prosthetic component is at a predetermined location within the body lumen; and

withdrawing the introducer to expand the prosthetic component to its decompressed size at the predetermined location within the body lumen.

27. (Original) The method of claim 25, wherein contacting said cord with fluid comprises the following steps:

aligning the outside circumference of the hem within the inside diameter of the body lumen; and

removing an impediment to the flow of fluid within the body lumen to said cord.

28. - 34. (Canceled)

35. (Previously Presented) A device for implantation in a body lumen comprising:

a prosthetic component comprising a graft having a hem formed on said graft, wherein said hem defines an interior space, and a stent disposed radially inside said graft; and

a cord disposed within said interior space adapted for expanding upon absorbing fluid for aiding in fixating said prosthetic component against said body lumen.

36. (Previously Presented) A device for implantation in a body lumen comprising:

a prosthetic component having a proximal end and a distal end and comprising a graft having a first hem formed on said graft at said distal end, wherein said hem defines a first interior space, and a second hem formed on said graft at said proximal end, wherein said second hem defines a second interior space;

a first cord disposed within said first interior space adapted for expanding upon absorbing fluid for aiding in fixating said prosthetic component against said body lumen; and

a second cord adapted for expanding upon absorbing fluid for aiding in fixating said prosthetic component against said body lumen disposed within said second interior space.

37. (Previously Presented) A device for implantation in a body lumen comprising:

a prosthetic component having a distal end and comprising a graft having a hem formed on said graft at said distal end, wherein said hem defines an interior space; and

a cord, disposed within said interior space adapted for expanding upon absorbing fluid for aiding in fixating said prosthetic component against said body lumen, wherein said cord is in a compressed state having a thickness less than thirty thousandths of an inch prior to being contacted with fluid.

38. (Previously Presented) A device for implantation in a body lumen comprising:

a prosthetic component comprising a graft having a hem formed on said graft, wherein said hem defines an interior space and said hem is sufficiently ductile to conform to irregular shapes; and

a cord disposed within said interior space adapted for expanding upon absorbing fluid for aiding in fixating said prosthetic component against said body lumen.

39. (Previously Presented) The device of claim 35, wherein said hem is positioned to allow said stent to protrude distally relative to said hem.

40. (Previously Presented) The device of claim 39, wherein at least one hoop of said stent is distal relative to said hem.

41. (Previously Presented) A device for implantation in a body lumen comprising:

a prosthetic component comprising a graft having a hem formed on said graft, wherein said graft has a first permeability at areas remote from said hem and a second permeability, greater than said first permeability, at said hem, and wherein said hem defines an interior space; and

a cord disposed within said interior space adapted for expanding upon absorbing fluid for aiding in fixating said prosthetic component against said body lumen.

42. (Previously Presented) A method of implanting a device in a body lumen comprising the steps of:

compressing said device into an introducer wherein said device comprises: a prosthetic component comprising a graft having a hem formed on said graft, wherein said hem defines an interior space and a cord disposed within said interior space for expanding upon absorbing said fluid;

inserting said introducer into said body lumen;

positioning said introducer such that said compressed prosthetic component is at a predetermined location within said body lumen;

withdrawing said introducer to expand the prosthetic component to its decompressed size at said predetermined location within the body lumen; and

contacting said cord with fluid to aid in fixating said prosthetic component against said body lumen.

43. (Previously Presented) A method of implanting a device in a body lumen comprising the steps of:

introducing said device into said body lumen wherein said device comprises: a prosthetic component comprising a graft having a hem formed on said graft, wherein said hem defines an interior space; and a cord disposed within said interior space for expanding upon absorbing said fluid to aid in fixating said prosthetic component against said body lumen;

aligning an outside circumference of the hem within an inside diameter of said body lumen; and

removing an impediment to a flow of a fluid within said body lumen to said cord, to allow said fluid to contact said cord.

44. (Previously Presented) The device of claim 1, wherein said cord consists of an absorbent material which absorbs fluid and expands as a result of the absorption of fluid.

45. (Previously Presented) The method of claim 25, wherein said cord consists of an absorbent material which, upon the contacting step, absorbs fluid and expands as a result of the absorption of fluid.

46. (Previously Presented) The device of claim 35, wherein said cord consists of an absorbent material which absorbs fluid and expands as a result of the absorption of fluid.

47. (Previously Presented) The device of claim 36, wherein said first and second cord consist of an absorbent material which absorbs fluid and expands as a result of the absorption of fluid.

48. (Previously Presented) The device of claim 37, wherein said cord consists of an absorbent material which absorbs fluid and expands as a result of the absorption of fluid.

49. (Previously Presented) The device of claim 38, wherein said cord consists of an absorbent material which absorbs fluid and expands as a result of the absorption of fluid.

50. (Previously Presented) The device of claim 41, wherein said cord consists of an absorbent material which absorbs fluid and expands as a result of the absorption of fluid.

51. (Previously Presented) The method of claim 42, wherein said cord consists of an absorbent material which, upon the contacting step, absorbs fluid and expands as a result of the absorption of fluid.

52. (Previously Presented) The method of claim 43, wherein said cord consists of an absorbent material which, upon said fluid contacting said cord, absorbs fluid and expands as a result of the absorption of fluid.